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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,538	04/20/2004	John C. Pulford	A0420/7017P1	3890
21127	7590	12/29/2004	EXAMINER	
KUDIRKA & JOBSE, LLP			COMSTOCK, DAVID C	
ONE STATE STREET			ART UNIT	PAPER NUMBER
SUITE 800				
BOSTON, MA 02109			3732	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/828,538	PULFORD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David Comstock	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 August 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 April 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>07/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "garter spring" in claims 3 and 21 is used by the claim to mean "a coiled spring that exerts an outward radial force", while the accepted meaning is "a coiled spring that exerts an inward radial force (i.e., a constricting or clamping force)." The term is indefinite because the specification does not clearly redefine the term. For examination purposes these claims have been considered as reciting a spring means for exerting an outward radial force.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-11, 13, 14, 19, 20, 22-27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Yuen (4,984,564).

Yuen discloses a surgical retractor device 10 comprising an inner ring 14, an outer ring 12, and an elongate sleeve 16 connected to and extending between the inner and outer rings (see Fig. 2; col. 2, lines 6-55; and col. 3, lines 4-21). The rings comprise fluid tight channels, with respect to the exterior of the device. The device includes a radial support structure 30 (see Figs. 3-5). Since the rings and sleeve are all connected to each other, the channels of the inner ring and outer ring can be considered part of the elongate sleeve. Nevertheless, since the rings comprise a discrete identifiable structure, namely rings, the channels defined within and by the rings can be considered discrete fluid tubes. Dilation of the rings results in an increase in the diameter of the device (cf. Figs. 1 and 2 or 4 and 5). The fluids used may be pressurized liquid or gas (see col. 4, lines 38-40 and 57-59). The device includes a check valve--i.e. a valve that restrains or inhibits a fluid, namely, the valves 18, 22, 26,28 having caps--in a fluid pathway between the pressurized source and the rings (see Figs. 1-5 and col. 3, line 66 - col. 4, line 4). The device also includes an output fluid pathway 22 (e.g., Fig. 1 and col. 3, lines 10-27). A method of using the device is disclosed (see col. 4, lines 34-66).

The device is inserted in an incision an undilated state whereupon it is inflated with pressurized air or fluid. After the surgical procedure has been completed, the fluid is vented from the rings through the output pathway in order to remove the device from the incision.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 21, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuen (4,984,564) in view of Brinkerhoff et al. (5,366,478; cited by Applicant).

Yuen discloses the claimed invention except for the springs. Brinkerhoff et al. disclose a similar device comprising flexible stiffening rings, i.e. springs, 19, in order to provide shape when the device is deflated and facilitate insertion into a body cavity (see Fig. 1 and col. 4, lines 28-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the retractor device of Yuen with springs, in view of Brinkerhoff et al., in order to provide shape when the device is deflated and facilitate insertion into a body cavity. With regard to the ring having separate ends in Yuen, it still would have been obvious to provide the device of Yuen with the springs, as set forth above, since it has been held that constructing a formerly

integral structure (i.e. the continuous ring springs of Brinkerhoff et al) in various elements (i.e. the ring having separate ends) involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Claims 12 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuen (4,984,564) in view of Kleaveland (3,863,639).

Yuen discloses the claimed invention except for explicitly disclosing that the pressure source can be a syringe. Kleaveland discloses a similar device that is pressurized with any of various different functionally equivalent pressurizing devices known in the art, e.g. a syringe (see Fig. 1 and col. 3, lines 45-60). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a syringe for any of numerous pressurizing means known in the art, in view of Kleaveland, as these were functionally equivalent pressurizing means known in the art at the time of the invention, and as such, would have merely required routine skill to implement.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,723,044 ('044). Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences involve only obvious modifications to the subject matter of claim 1 of '044.

Claim 1 of '044 discloses the inner and outer rings and the elongate sleeve, as well as the pre-loaded rotational torque. Claim 1 does not disclose the rings having a minimum diameter of 20 cm. With regard to claims 15 and 16, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the rings with a diameter of 20 cm or with any of numerous other dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. With regard to claims 17 and 18, it also would have been obvious to form the rings of an elastic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.

*DC*

D. Comstock  
27 December 2004

*Cary E. O'Connor*  
Cary E. O'Connor  
Primary Examiner